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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/643,982	08/23/2000	James A. St. Ville	2656-21	2642

7590 01/29/2003

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EXAMINER	
THANGAVELU, KANDASAMY	
ART UNIT	**PAPER NUMBER**
2123	

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/643,982	ST. VILLE, JAMES A.
	Examiner	Art Unit
	Kandasamy Thangavelu	2123

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 October 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Introduction

1. This communication is in response to the Applicant's Amendment mailed on October 24, 2002. Claims 1-42 of the application are pending.

Response to Amendments

2. Applicant's amendments, filed on October 24, 2002 have been considered. Claim rejections under obviousness double patenting have been modified in response to Applicant's arguments.

The art rejections are based on the additional prior art included in this office action. Therefore, this office action is made non-final.

Drawings

3. Acknowledgment is made of the proposed changes to the drawing sent by the Applicant on October 24, 2002. The proposed changes are accepted.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1 of U.S. Patent No. 6,263,252 ('252 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claim 1 teaches a method for manufacturing an object having a potential { x } that is generated in response to a field { f } applied thereto, the method comprising the steps of:

generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements and specifying values for the field { f } and potential { x } relative to the finite elements;

specifying that the material properties of the finite elements have a particular symmetry;

calculating a material property matrix [k] based on the relationship { f }=[k] { x }and the specified symmetry;

extracting material property coefficients from the material property matrix [k] for each finite element in the computerized mathematical model;

comparing the extracted material property coefficients to material property coefficients for known materials to match the extracted material property coefficients to the material property coefficients for known materials;

determining manufacturing parameters for controlling manufacturing equipment based on the matched material property coefficients; and

controlling the manufacturing equipment in accordance with the determined manufacturing parameters to thereby manufacture the object.

Claim 1 of the '252 patent teaches calculating a material property matrix [k] based on the relationship { f }=[k] { x }. Claim 1 of the '252 patent does not expressly teach specifying that the material properties of the finite elements have a particular symmetry; and

calculating a material property matrix [k] based on the relationship { f }=[k] { x } and the specified symmetry.

However, **WU** (U.S. Patent 5,654,077) teaches that materials can have isotropic, orthotropic or anisotropic properties. Isotropic property results in same material property in all directions thus providing symmetry in material property (Col 1, Line 65 to Col 2, Line 5). Isotropic property is often specified in materials as that eliminates weak spots in the structural element and provides

maximum weight reduction in a structural component (Col 5, lines 20-28). So it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to identify that the method of claim 1 is same as the method taught in Claim 1 (Col 17, Line 59 to Col 18, Line 16) of the '252 patent, with materials having isotropic property.

6. Claim 25 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 19 of U.S. Patent No. 6,263,252 ('252 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claim 25 teaches a computer-implemented method for determining machine control instructions for manufacturing an object having a potential { x } that is generated in response to a field {f} applied thereto, the method comprising the steps of:

generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements and specifying values of the field { f } and potential { x } relative to the finite elements;

specifying that the material properties of the finite elements have a particular symmetry;

calculating a material property matrix [k] based on the relationship {f}=[k]{x] and the specified symmetry;

extracting material property coefficients from the material property matrix [k] for each finite element in the computerized mathematical model;

comparing the extracted material property coefficients to material property coefficients for known materials to match the extracted material property coefficients to the material property coefficients for known materials;

determining manufacturing parameters for controlling manufacturing equipment based on the matched material property coefficients; and

generating machine control instructions for controlling the manufacturing equipment in accordance with the manufacturing parameters.

Claim 19 of the '252 patent teaches calculating a material property matrix [k] based on the relationship { f }=[k] { x }. Claim 19 of the '252 patent does not expressly teach specifying that the material properties of the finite elements have a particular symmetry; and

calculating a material property matrix [k] based on the relationship { f }=[k] { x } and the specified symmetry.

However, **WU** (U.S. Patent 5,654,077) teaches that materials can have isotropic, orthotropic or anisotropic properties. Isotropic property results in same material property in all directions thus providing symmetry in material property (Col 1, Line 65 to Col 2, Line 5). Isotropic property is often specified in materials as that eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, lines 20-28). So it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to identify that the method of claim 25 is same as the method taught in Claim 19 (Col 19, Lines 16-40) of the '252 patent, with materials having isotropic property

7. Claim 41 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 34 of U.S. Patent No. 6,263,252 ('252 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claim 41 teaches a method for manufacturing an object for which a defined field { f } generates a potential {x} in response thereto, the method comprising the steps of:

(1) generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements;

(2) specifying values of the field { f } and the potential { x } relative to the finite elements;

(3) specifying that the material properties of the finite elements have a particular symmetry;

(4) calculating a material property matrix [k] based on the relationship to { f }=[k] { x } and the specified symmetry, wherein the material property matrix [k] comprises a plurality of values each corresponding to one or more material property coefficients;

(5) comparing each of the plurality of values in the material property matrix [k] to known material properties and, responsive to a match, selecting a corresponding manufacturing process parameter, wherein the selected manufacturing process parameter is usable for controlling composite manufacturing equipment if the matched known material property is a material property for a composite material; and

(6) controlling the composite manufacturing equipment in accordance with the selected manufacturing process parameters to thereby manufacture the object.

Claim 34 of the '252 patent teaches calculating a material property matrix [k] based on the relationship { f }=[k] { x }. Claim 1 of the '252 patent does not expressly teach specifying that the material properties of the finite elements have a particular symmetry; and

calculating a material property matrix [k] based on the relationship { f }=[k] { x } and the specified symmetry.

However, **WU** (U.S. Patent 5,654,077) teaches that materials can have isotropic, orthotropic or anisotropic properties. Isotropic property results in same material property in all directions thus providing symmetry in material property (Col 1, Line 65 to Col 2, Line 5). Isotropic property is often specified in materials as that eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, lines 20-28). So it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to identify that the method of claim 41 is same as the method taught in Claim 34 (Col 20, Lines 34-57) of the '252 patent, with materials having isotropic property

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

9. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1, 2, 4-10, 21-27 and 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077).

10.1 **VI** teaches a method and apparatus for manufacturing a prosthesis having optimized response characteristics. Specifically, as per Claim 1, **VI** teaches a method for manufacturing an object having a potential { x } that is generated in response to a field { f } applied (Col 4, Lines 43-45 and Col 6, Lines 44-53); the method comprising the steps of:

generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements (Col 4, Lines 46-49); and

specifying values for the field { f } and potential { x } relative to the finite elements (Col 4, Lines 50-51);

extracting material property coefficients from the material property matrix [k] for each finite element in the computerized mathematical model (Col 4, Lines 53-55);

comparing the extracted material property coefficients to material property coefficients for known materials to match the extracted material property coefficients to the material property coefficients for known materials (Col 4, Lines 55-59);

determining manufacturing parameters for controlling manufacturing equipment based on the matched material property coefficients (Col 4, Lines 59-61; Col 11, Lines 35-38); and

controlling the manufacturing equipment in accordance with the determined manufacturing parameters to thereby manufacture the object (Col 4, Lines 61-62; Col 12, Lines 13-18; Col 14, Lines 44-48).

VI teaches that the method includes specifying the material properties of the finite elements (Col 4, Lines 51-52). **VI** does not expressly teach that the method includes specifying that the material properties of the finite elements have a particular symmetry. **WU** teaches that the method includes specifying that the material properties of the finite elements have a particular symmetry (Col 1, Lines 65-67 and Col 5, Lines 26-33), as both **VI** and **WU** deal with material properties of multimaterial laminate, and the symmetry eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU** specifying that the material properties of the finite elements have a particular symmetry, as both **VI** and **WU** deal with material properties of multimaterial laminate, and the symmetry would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component.

VI teaches that the method includes calculating a material property matrix [k] based on the relationship { f }=[k] { x } (Col 4, Lines 51-52). **VI** does not expressly teach that the method includes calculating a material property matrix [k] based on the relationship { f }=[k] { x }and the specified symmetry. **WU** teaches that the method includes calculating a material property matrix [k] based on the specified symmetry (Col 1, Lines 65-67 and Col 5, Lines 26-33), as both **VI** and **WU** deal with material properties of multimaterial laminate, and the symmetry eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU** that included calculating a material property matrix [k] based on the specified symmetry, as both **VI** and **WU** deal with material properties of multimaterial laminate, and the symmetry would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component.

10.2 As per Claim 2, **VI** and **WU** teach the method of Claim 1. **VI** does not expressly teach that the material properties of the finite elements are specified to be isotropic. **WU** teaches that the material properties of the finite elements are specified to be isotropic (Col 5, Lines 26-33), as that eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU**, as that would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component.

10.3 As per Claim 4, **VI** and **WU** teach the method of Claim 1. **VI** also teaches that the step of generating a computerized mathematical model of the object includes determining the smallest volume increment that can be manufactured using the composite manufacturing equipment. (Col 13, Lines 1-8 and Col 13, Lines 21-23).

10.4 As per Claim 5, **VI** and **WU** teach the method of Claim 1. **VI** also teaches that the field { f } is a mechanical force field and the potential { x } is a displacement. (Col 7, Lines 53-67).

10.5 As per Claim 6, **VI** and **WU** teach the method of Claim 1. **VI** also teaches that the field {f} is an electric current field and the potential { x } is a voltage. (Col 7, Lines 53-67).

10.6 As per Claim 7, **VI** and **WU** teach the method of Claim 1. **VI** also teaches that the field {f} is a magnetic field and the potential { x } is a magnetic vector potential. (Col 7, Lines 53-67).

10.7 As per Claim 8, **VI** and **WU** teach the method of Claim 1. **VI** also teaches that the field {f} is a thermal flux field and the potential { x } is a temperature. (Col 7, Lines 53-67).

10.8 As per Claim 9, **VI** and **WU** teach the method of Claim 1. **VI** also teaches that the field { f } is a fluid velocity field and the potential {x} is a fluid potential. (Col 7, Lines 53-67).

10.9 As per Claim 10, **VI** and **WU** teach the method of Claim 1. **VI** also teaches that the step of controlling the manufacturing equipment comprises controlling a composite manufacturing equipment for manufacturing a composite material. (Col 12, Lines 13-18 and Col 12, Lines 23-29).

10.10 As per Claim 21, **VI** and **WU** teach the method of Claim 1. **VI** also teaches that the object being manufactured is a prosthetic implant for replacing a body part and the force {f} and displacement {x}are specified based on the in vivo forces applied to the body part to be replaced and the in vivo displacements generated in the body part to be replaced when the forces are applied (Col 8, Lines 23-35 and Col 8, Lines 39-44).

10.11 As per Claim 22, **VI** and **WU** teach the method of Claim 1. **VI** teaches an article of manufacture made in accordance with the method of claim 1 (Col 6, Lines 58-62);

the article is selected from the group consisting of an automobile part, an aircraft part, a prosthetic implant, a golf club shaft, a tennis racket, a bicycle frame, and a fishing pole (Col 6, Lines 58-62); and

different portions of the article have different material properties corresponding to the matched extracted material property coefficients for known materials (Col 4, Lines 46-59).

10.12 As per Claim 23, **VI** and **WU** teach the method of Claim 1. **VI** teaches a prosthetic implant manufactured in accordance with the method of claim 1 (Col 8, Lines 23-35 and Col 8, Lines 39-44).

10.13 As per Claim 24, **VI** and **WU** teach the method of Claim 1. **VI** teaches a golf club manufactured in accordance with the method of claim 1. (Col 6, Lines 58-62).

10.14 As per Claim 25, **VI** teaches a computer-implemented method for determining machine control instructions for manufacturing an object having a potential { x } that is generated in response to a field {f} applied (Col 14, Lines 44-48 and Col 6, Lines 44-53); the method comprising the steps of:

generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements (Col 4, Lines 46-49);

specifying values for the field { f } and potential { x } relative to the finite elements (Col 4, Lines 50-51);

extracting material property coefficients from the material property matrix [k] for each finite element in the computerized mathematical model (Col 4, Lines 53-55);

comparing the extracted material property coefficients to material property coefficients for known materials to match the extracted material property coefficients to the material property coefficients for known materials (Col 4, Lines 55-59);

determining manufacturing parameters for controlling manufacturing equipment based on the matched material property coefficients (Col 4, Lines 59-61; Col 11, Lines 35-38); and

generating machine control instructions for controlling the manufacturing equipment in accordance with the manufacturing parameters (Col 14, Lines 44-48).

VI does not expressly teach that the method includes specifying that the material properties of the finite elements have a particular symmetry. **WU** teaches that the method includes specifying that the material properties of the finite elements have a particular symmetry (Col 1, Lines 65-67 and Col 5, Lines 26-33), as that eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU** specifying that the material properties of the finite elements have a particular symmetry, as that would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component.

VI teaches that the method includes calculating a material property matrix [k] based on the relationship { f }=[k] { x } (Col 4, Lines 51-52). **VI** does not expressly teach that the method includes calculating a material property matrix [k] based on the relationship { f }=[k] { x }and the specified symmetry. **WU** teaches that the method includes calculating a material property matrix [k] based on the specified symmetry (Col 1, Lines 65-67 and Col 5, Lines 26-33), as that eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU** that included calculating a material property matrix [k] based on the specified symmetry, as that would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component.

10.15 As per Claim 26, **VI** and **WU** teach the method of Claim 25. **VI** also teaches that the object being manufactured is a prosthetic implant for replacing a body part and the force {f} and displacement {x}are specified based on the in vivo forces applied to the body part to be replaced and the in vivo displacements generated in the body part to be replaced when the forces are applied (Col 8, Lines 23-35 and Col 8, Lines 39-44).

10.16 As per Claim 27, **VI** and **WU** teach the method of Claim 25. **VI** also teaches that the step of generating machine control instructions comprises generating machine control instructions for controlling composite manufacturing equipment for manufacturing a composite material. (Col 14, Lines 44-48 and Col 12, Lines 23-29).

10.17 As per Claim 38, **VI** and **WU** teach the method of Claim 25. **VI** also teaches a computer system programmed to perform the method of claim 25. (Col 13, Line 53 to Col 14, Line 58 and Col 14, Lines 59-61).

10.18 As per Claim 39, **VI** and **WU** teach the method of Claim 25. **VI** also teaches a control system programmed with machine control instructions for controlling composite manufacturing equipment to manufacture a composite object, where the machine control instructions are generated in accordance with the method of claim 25. (Col 12, Lines 23-25 and Col 12, Lines 39-42).

10.19 As per Claim 40, **VI** and **WU** teach the method of Claim 25. **VI** also teaches composite manufacturing equipment comprising a control system programmed with machine control instructions for controlling the composite manufacturing equipment to manufacture a composite object, where the machine control instructions are generated in accordance with the method of claim 25. (Fig. 10; Col 12, Lines 39-42 and Col 15, Lines 28-42).

10.20 As per Claim 41, **VI** teaches a method for manufacturing an object for which a defined field { f } generates a potential {x} in response (Col 14, Lines 44-48 and Col 6, Lines 44-53); the method comprising the steps of:

generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements (Col 4, Lines 46-49;

specifying values of the field { f } and potential { x } relative to the finite elements (Col 4, Lines 50-51);

wherein the material property matrix [k] comprises a plurality of values each corresponding to one or more material property coefficients (Col 4, Lines 53-59);

comparing each of the plurality of values in the material property matrix [k] to known material properties (Col 4, Lines 55-59);

responsive to a match, selecting a corresponding manufacturing process parameter, wherein the selected manufacturing process parameter is usable for controlling composite manufacturing equipment if the matched known material property is a material property for a composite material (Col 4, Lines 59-61 and Col 12, Lines 23-25); and

controlling the composite manufacturing equipment in accordance with the selected manufacturing process parameters to thereby manufacture the object (Col 14, Lines 44-48).

VI does not expressly teach that the method includes specifying that the material properties of the finite elements have a particular symmetry. **WU** teaches that the method includes specifying that the material properties of the finite elements have a particular symmetry (Col 1, Lines 65-67 and Col 5, Lines 26-33), as that eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU** specifying that the material properties of the finite elements have a particular symmetry, as that would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component.

VI teaches that the method includes calculating a material property matrix [k] based on the relationship { f }=[k] { x }(Col 4, Lines 51-52). **VI** does not expressly teach that the method includes calculating a material property matrix [k] based on the relationship { f }=[k] { x }and the specified symmetry. **WU** teaches that the method includes calculating a material property matrix [k] based on the specified symmetry (Col 1, Lines 65-67 and Col 5, Lines 26-33), as that eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU** that included calculating a material property matrix [k] based on the specified

symmetry, as that would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component.

10.21 As per Claim 42, **VI** and **WU** teach the method of Claim 41. **VI** also teaches that the object being manufactured is a prosthetic implant for replacing a body part and the force {f} and displacement {x} are specified based on the in vivo forces applied to the body part to be replaced and the in vivo displacements generated in the body part to be replaced when the forces are applied (Col 8, Lines 23-35 and Col 8, Lines 39-44).

11. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077), and further in view of **Legere (LE)** (U.S. Patent 6,087,571).

11.1 As per Claim 3, **VI** and **WU** teach the method of Claim 1. **VI** and **WU** do not expressly teach that the material properties of the finite elements are specified to be transversely isotropic. **LE** teaches that the material properties of the finite elements are specified to be transversely isotropic (Col 6, Lines 55-65), so the material will have enhanced properties in the draw direction and properties similar to those of the undrawn polymer in all directions transverse to the draw direction (Col 6, Lines 53-55). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** and **WU** with method of **LE** that specifies that the material properties of the finite elements be transversely isotropic, so

the material would have enhanced properties in the draw direction and properties similar to those of the undrawn polymer in all directions transverse to the draw direction.

12. Claims 11 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077), and further in view of **Castanie et al (CA)** (U.S. Patent 6,290,889).

12.1 As per Claim 11, **VI** and **WU** teach the method of Claim 10. **VI** does not expressly teach that the composite material comprises structural fibers laminated in a matrix. **WU** teaches the composite material comprises structural fibers laminated in a matrix (Col 1, Lines 15-20; Col 9, Lines 42-43). As per **CA** (Col 1, Lines 11-13), this facilitates producing an article having high strength, accuracy and temperature resistance characteristics. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **WU** that specifies that the composite material comprises structural fibers laminated in a matrix, since as per CA that would facilitate producing an article having high strength, accuracy and temperature resistance characteristics.

12.2 As per Claim 28, it is rejected based on the same reasoning as Claim 11, supra. Claim 28 is a method claim reciting the same limitation as Claim 11, as taught throughout by **VI, WU** and **CA.**

13. Claims 12 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), and further in view of **Abatangelo et al. (AB)** (WO 97/18842).

13.1 As per Claim 12, **VI, WU** and **CA** teach the method of Claim 11. **VI, WU** and **CA** do not expressly teach that the matrix includes biologic material. **AB** teaches that the matrix includes biologic material (Page 3, Para 4), since it is possible to seed and grow fibroblasts enabling production of an extracellular matrix similar to that of natural connective tissue (Page 2, Para 4). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU** and **CA** with method of **AB** that specifies that the matrix included biologic material, since it would be possible to seed and grow fibroblasts enabling production of an extracellular matrix similar to that of natural connective tissue.

13.2 As per Claim 29, it is rejected based on the same reasoning as Claim 12, <u>supra.</u> Claim 29 is a method claim reciting the same limitation as Claim 12, as taught throughout by **VI, WU, CA** and **AB.**

14. Claims 13 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), and further in view of **Johnson et al. (JO)** (U.S. Patent 6,296,667).

14.1 As per Claim 13, **VI, WU** and **CA** teach the method of Claim 11. **VI, WU** and **CA** do not expressly teach that the matrix includes bone. **JO** teaches that the matrix includes bone (Col 6, Lines 13-25), since that provides an osteoconductive matrix providing a scaffold for bone ingrowth and osteoinductive factors providing chemical agents that induce bone regeneration and repair (Col 1, Lines 27-30) It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU** and **CA** with method of **JO** that specifies that the matrix included bone, since that would provide an osteoconductive matrix providing a scaffold for bone ingrowth and osteoinductive factors providing chemical agents that induce bone regeneration and repair.

14.2 As per Claim 30, it is rejected based on the same reasoning as Claim 13, supra. Claim 30 is a method claim reciting the same limitation as Claim 13, as taught throughout by **VI, WU, CA** and **JO.**

15. Claims 14 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), and further in view of **Bonadio et al. (BO)** (U.S. Patent 5,942,496).

15.1 As per Claim 14, **VI, WU** and **CA** teach the method of Claim 11. **VI, WU** and **CA** do not expressly teach that the matrix includes crushed bone. **BO** teaches that the matrix includes

crushed bone (Col 58, Lines 29-34), since this material has the ability to simulate new bone formation (Col 58, Lines 35-36). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU** and **CA** with method of **BO** that specifies that the matrix included crushed bone, since this material has the ability to simulate new bone formation.

15.2 As per Claim 31, it is rejected based on the same reasoning as Claim 14, supra. Claim 31 is a method claim reciting the same limitation as Claim 14, as taught throughout by **VI, WU, CA** and **BO.**

16. Claims 15 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Warren, Jr. (WA)** (U.S. Patent 6,348,042).

16.1 As per Claim 15, **VI, WU** and **CA** teach the method of Claim 11. **VI, WU** and **CA** do not expressly teach that the matrix includes co-factors. **WA** teaches that the matrix includes co-factors (abstract; Col 2, Lines 38-52), as the cofactors activate the enzyme impregnated in the lumen, within the biological system (Col 3, Lines 10-12). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU** and **CA** with method of **WA** that specifies that the matrix included co-factors, as the cofactors activate the enzyme impregnated in the lumen, within the biological system.

16.2 As per Claim 32, it is rejected based on the same reasoning as Claim 15, supra. Claim 32 is a method claim reciting the same limitation as Claim 15, as taught throughout by **VI, WU, CA** and **WA.**

17. Claims 16 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (VI) (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Tadros et al.** (TA) (U.S. Patent 6,121,033).

17.1 As per Claim 16, **VI, WU** and **CA** teach the method of Claim 11. **VI, WU** and **CA** do not expressly teach that the matrix includes biological cells. **TA** teaches that the matrix includes biological cells. (Col 14, Lines 39-52), as biological cells which are completely degradable into biomass without having toxic effect on the microbes (Col 14, Lines 41-43). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU** and **CA** with method of **TA** that specifies that the matrix included biological cells, as biological cells which are completely degradable into biomass without having toxic effect on the microbes.

17.2 As per Claim 33, it is rejected based on the same reasoning as Claim 16, supra. Claim 33 is a method claim reciting the same limitation as Claim 16, as taught throughout by **VI, WU, CA** and **TA.**

18. Claims 17 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Slaikeu (SL)** (U.S. Patent 6,231,590).

18.1 As per Claim 17, **VI, WU** and **CA** teach the method of Claim 11. **VI, WU** and **CA** do not expressly teach that the matrix includes bio-active materials. **SL** teaches that the matrix includes bio-active materials (Col 7, Lines 15-21), since such materials have properties to reduce friction, provide a therapeutic for local or blood borne delivery and enhance thrombosis, coagulation or platelet activity (Col 7, Lines 8-11). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU** and **CA** with method of **SL** that specifies that the matrix included bio-active materials, since that would describe the manufacturing method for materials including bio-active materials which are useful to reducing friction, providing a therapeutic for local or blood delivery etc.

18.2 As per Claim 34, it is rejected based on the same reasoning as Claim 17, supra. Claim 34 is a method claim reciting the same limitation as Claim 17, as taught throughout by **VI, WU, CA** and **SL.**

19. Claims 18 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077) and

Castanie et al. (CA) (U.S. Patent 6,290,889), further in view of **Hermann (HE)** (U.S. Patent 5,098,621).

19.1 As per Claim 18, **VI, WU** and **CA** teach the method of Claim 11. **VI, WU** and **CA** do not expressly teach that the matrix includes medications. **HE** teaches that the matrix includes medications (Col 9, Lines 49-55), as medications could be dispensed for the dressings (Col 9, Lines 51-52). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU** and **CA** with method of **HE** that specifies that the matrix included medications, since medications could be dispensed for the dressings.

19.2 As per Claim 35, it is rejected based on the same reasoning as Claim 18, <u>supra.</u> Claim 35 is a method claim reciting the same limitation as Claim 18, as taught throughout by **VI, WU, CA** and **HE.**

20. Claims 19 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Phipps et al. (PH)** (U.S. Patent 6,289,242).

20.1 As per Claim 19, **VI, WU** and **CA** teach the method of Claim 11. **VI, WU** and **CA** do not expressly teach that the matrix includes antibiotics. **PH** teaches that the matrix includes

antibiotics (Col 16, Lines 46-50), since antibiotics could be introduced into the host for use as anti-infectives (Col 16, Lines 46-50). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI**, **WU** and **CA** with method of **PH** that specifies that the matrix included antibiotics, since antibiotics could be introduced into the host for use as anti-infectives.

20.2 As per Claim 36, it is rejected based on the same reasoning as Claim 19, supra. Claim 36 is a method claim reciting the same limitation as Claim 19, as taught throughout by **VI, WU, CA** and **PH.**

21. Claims 20 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (**VI**) (U.S. Patent 5,594,651) in view of **Wu et al.** (**WU**) (U.S. Patent 5,654,077) and **Castanie et al.** (**CA**) (U.S. Patent 6,290,889), further in view of **Mavity et al.** (**MA**) (U.S. Patent 6,248,057).

21.1 As per Claim 20, **VI, WU** and **CA** teach the method of Claim 11. **VI** does not expressly teach that the matrix includes radioactive materials. **MA** teaches that the matrix includes radioactive materials (Col 2, Lines 1-5), since they are useful for a variety of medical purposes, being particularly suitable for treatment of cancer (Abstract). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **MA** that specifies that the matrix included radioactive materials, since they are useful for a variety of medical purposes, being particularly suitable for treatment of cancer.

21.2 As per Claim 37, it is rejected based on the same reasoning as Claim 20, supra. Claim 37 is a method claim reciting the same limitation as Claim 20, as taught throughout by **VI, WU, CA** and **MA.**

Applicant's Arguments

22. The applicants argue the following:

(1) the concept in Wu et al. of searching distribution patterns would not have suggested that the method of St. Ville be modified to specify a particular symmetry;

(2) Legere merely states that the described uniaxially oriented materials may be transversely isotropic; there is no mention of volume elements in a finite element model nor any symmetry;

(3) Rauscher merely states that the human heart may be paced using an in vitro biological material; there is no mention of incorporating such material in a matrix into which structural fibres are laminated;

(4) Johnson et al. disclose a porous article used as a bone substitute material; there is no teaching of incorporating bone in a matrix into which structural fibres are laminated;

(5) Wack merely describes that crushed bone may be used in a femoral activity; there is no suggestion of incorporating crushed bone in a matrix into which structural fibres are laminated;

(6) Warren merely states that enzymes impregnated into the interior of the lumen of a catheter require the presence of co-factors; applicant does not understand the matrix to be a matrix into which structural fibres are laminated;

(7) Tadros et al. does not teach incorporating biological cells into a matrix of composite material;

(8) Sleiku does not teach incorporating bioactive materials in a matrix into which structural fibres are laminated;

(9) Hermann does not teach incorporating medications in a matrix into which structural fibres are laminated;

(10) Phipps et al. does not teach incorporating antibiotics in a matrix into which structural fibres are laminated;

(11) Mavity et al. states that a radioisotope may be bound to a biodegradeable polymeric matrix; there is no disclosure that this matrix is the one into which structural fibres are laminated.

Examiner's reply

23. As per the applicants' arguments, the applicant's attention is requested to the corresponding claim rejections. In addition, the following explanation is provided to further explain the examiner's position.

23.1 In response to the applicant's argument that "the concept in Wu et al. of searching distribution patterns would not have suggested that the method of St. Ville be modified to specify

a particular symmetry", the examiner respectfully disagrees. Both **VI** and **WU** deal with material properties of multimaterial laminate, and the symmetry would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component (**WU**: Col 5, Lines 27-28).

23.2 In response to the applicant's argument that "Legere merely states that the described uniaxially oriented materials may be transversely isotropic; there is no mention of volume elements in a finite element model nor any symmetry", the examiner requests the applicant's attention to the fact that transversely isotropic is a material property and symmetry is another material property; finite element model is a computer based analysis technique to study the behavior of objects with different properties; in finite element analysis, by varying the material properties of the objects strikingly different effects could be achieved (**OB**: U.S. Patent 6,456,289: Col 5, Lines 31-35 and Col 7, Lines 54-59)

23.3 The applicant's argument that "Rauscher merely states that the human heart may be paced using an in vitro biological material; there is no mention of incorporating such material in a matrix into which structural fibres are laminated" appears to be correct. So the examiner has used a new reference (**AB**). **AB** teaches that the matrix includes biologic material (Page 3, Para 4), since it is possible to seed and grow fibroblasts enabling production of an extracellular matrix similar to that of natural connective tissue (Page 2, Para 4).

23.4 In response to the applicant's argument that "Johnson et al. disclose a porous article used as a bone substitute material; there is no teaching of incorporating bone in a matrix into which structural fibres are laminated", the examiner requests the applicant's attention to the fact that Johnson et al. do use morselized bone of the patient, as shown in Col 6, Lines 13-25, since that provides an osteoconductive matrix providing a scaffold for bone ingrowth and osteoinductive factors providing chemical agents that induce bone regeneration and repair (Col 1, Lines 27-30).

23.5 In response to the applicant's argument that "Wack merely describes that crushed bone may be used in a femoral activity; there is no suggestion of incorporating crushed bone in a matrix into which structural fibres are laminated", the examiner has used a new reference (**BO**). **BO** teaches that the matrix includes crushed bone (Col 58, Lines 29-34), since this material has the ability to simulate new bone formation (Col 58, Lines 35-36).

23.6 In response to the applicant's argument that "Warren merely states that enzymes impregnated into the interior of the lumen of a catheter require the presence of co-factors; applicant does not understand the matrix to be a matrix into which structural fibres are laminated", the examiner requests applicants attention to **WA**: Abstract and Col 2, Lines 38-52. WA mentions the matrix forming system, matrix layer of enzymes and a matrix containing enzymes. So this is a matrix of composite materials into which structural fibres are laminated.

23.7 In response to the applicant's argument that "Tadros et al. does not teach incorporating biological cells into a matrix of composite material", the examiner respectfully disagrees; the

examiner requests the applicant's attention to the matrix taught by Tadros et al. (Col 14, Lines 39-52). **TA** teaches a matrix containing biological cells, which are completely degradable, and the matrix could contain polymers and pharmaceutical compounds.

23.8 In response to the applicant's argument that "Sleiku does not teach incorporating bioactive materials in a matrix into which structural fibres are laminated", the examiner respectfully disagrees; the examiner requests the applicant's attention to the layers taught by Sleiku (Col 7, Lines 15-21). Sleiku teaches that multiple layers could be arranged with different materials to achieve properties to reduce friction, provide a therapeutic for local or blood borne delivery and enhance thrombosis, coagulation or platelet activity. It would be obvious to one of ordinary skill in the art that these layers would be arranged in a matrix.

23.9 In response to the applicant's argument that "Hermann does not teach incorporating medications in a matrix into which structural fibres are laminated", the examiner respectfully disagrees; the examiner requests the applicant's attention to the matrix taught by Hermann (Col 9, Lines 49-55). HE teaches that the matrix could be impregnated with composite dispensing material for releasing medications and active ingredient particles for releasing setting agents.

23.10 In response to the applicant's argument that "Phipps et al. does not teach incorporating antibiotics in a matrix into which structural fibres are laminated", the examiner respectfully disagrees; the examiner requests the applicant's attention to the matrix taught by Phipps et al.

(Col 16, Lines 46-50). PH teaches that a variety active agents may be combined with the matrix including antibiotics.

23.11 In response to the applicant's argument that "Mavity et al. states that a radioisotope may be bound to a biodegradeable polymeric matrix; there is no disclosure that this matrix is the one into which structural fibres are laminated", the examiner requests applicants attention to **MA**: Col 2, Lines 1-5. MA mentions that radioisotope may be bound to a biodegradable polymeric matrix to provide controlled release of the radioactive material over time; this is particularly suitable for treatment of solid tumors. So this is a matrix of composite materials into which structural fibres are laminated.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure.

The following patents are cited to further show the state of the art with respect to manufacturing composite materials using computer integrated manufacturing.

1. Abatangelo et al., "A biological material comprising … acid derivative", International application, WO 97/18842, May 1997.
2. Bonadio et al., "Methods and compositions for multiple gene transfer into bone cells", U.S. Patent 5,942,496, August 1999.

3. O'Brien et al., "Animation system and method for animating object feature", U.S. Patent 6,456,289, September 2002.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kandasamy Thangavelu whose telephone number is 703-305-0043. The examiner can normally be reached on Monday through Friday from 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Teska, can be reached on (703) 305-9704. The fax phone number for the organization where this application or proceeding is assigned is 703-746-7329.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-9600.

K. Thangavelu
Art Unit 2123
January 9, 2003

KEVIN J. TESKA
SUPERVISORY
PATENT EXAMINER